URGENT FIELD SAFETY CORRECTIVE ACTION (EMEA/M-001)
MAXTER ENTRAL* ENFIT® NASOGASTRIC (NG) FEEDING TUBES

17 October 2017

Dear Valued Maxter Products Customer,

The purpose of this letter is to advise you that Maxter is recalling all product codes and production lots of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector.

What is the reason for this Voluntary Medical Device Field Safety Action (i.e., Recall)?
Maxter Catheters has received four reports indicating that the White Cap that is attached to the retaining strap of the ENFit® Connector found on ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit®Connector (i.e., Purple Connector) separated from the retaining strap due to excessive patient manipulation (see following page for representative photo). This situation may result in the patient (primarily Paediatric) placing the cap into their mouth, which could cause a choking hazard. In all instances, the cap separated from the retention strap during feeding.

Although the reported risk of occurrence is rare (i.e., less than 4 per million) this notice is intended to inform all users of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector about this potential choking hazard and requests to quarantine and return (RECALL) of all unused impacted products summarized in the table below.

Which Products are impacted?
The products impacted include only the model numbers of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector (i.e., Purple Connector) products summarized in the following table.

Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
503…	503-04-4-B10	Not Applicable	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Fr xx - Lg yy cm
	503-04-5	Not Applicable	
	503-06	Not Applicable	
	503-06-5	Not Applicable	
	503-08	Not Applicable	
	503-08-5	Not Applicable	
	503-08-B10	Not Applicable	
	503-10	Not Applicable	
	503-10-5	Not Applicable	
503T…	503T04	NST4-120	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Fr xx - Lg yy cm
	503T04-4	NST4-40	
	503T04-5	NST4-50	
	503T04-5SL	NST4-50	
	503T04-8	NST4-80	
	503T04-16	NST4-160	
	503T05	NST5-120	
	503T05-4	NST5-40	
	503T05-5	NST5-50	
	503T05-8	NST5-80	
	503T06	NST6-120	

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Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
503T…	503T06-4	NST6-40	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Fr xx - Lg yy cm
	503T06-5	NST6-50	
	503T06-5SL	NST6-50	
	503T06-8	NST6-80	
	503T06-10	NST6-100	
	503T06-16	NST6-160	
	503T08	NST8-120	
	503T08-4	NST8-40	
	503T08-5	NST8-50	
	503T08-5SL	NST8-50	
	503T08-6	NST8-60	
	503T08-8	NST8-80	
	503T08-16	NST8-160	
	503T10	NST10-120	
	503T10-4	NST10-40	
	503T10-5	NST10-50	
	503T10-5SL	NST10-50	
	503T10-8	NST10-80	
	503T12	NST12-120	
	503T12-8	NST12-80	
	503T14-8	NST14-80	
503TL…	503TL04-5	NST4-50W	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Tungsten weighted Fr xx - Lg yy cm
	503TL06	NST6-120W	
	503TL06-5	NST6-50W	
	503TL06-8	NST6-80W	
	503TL08	NST8-120W	
	503TL08-5	NST8-50W	
	503TL08-8	NST8-80W	
	503TL10-8	NST10-80W	
	503TL12-8	NST12-80W	
505…	505-04	PVC4-120	ENTRAL* - ENFit® Nasogastric feeding tube PVC LORX Fr xx - Lg yy cm
	505-04-4	PVC4-40	
	505-04-5	PVC4-50	
	505-06	PVC6-120	
	505-06-4	PVC6-40	
	505-06-5	PVC6-50	
	505-08	PVC8-120	
	505-08-4	PVC8-40	
	505-08-5	PVC8-50	
	505-10	PVC10-120	
	506-04	NST4-120SIL	ENTRAL* - ENFit® Nasogastric feeding tube
	506-06	NST6-120SIL	

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Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
506…	506-08	NST8-120SIL	Silicone ORX Fr xx - Lg yy cm
	506-08-5	NST8-50SIL	
	506-09	NST9-120SIL	
	506-10	NST10-120SIL	
506L…	506L04-85	NST4-85WSIL	ENTRAL* - ENFit® Nasogastric feeding tube Silicone ORX Tungsten weighted Fr xx - Lg yy cm
	506L06-85	NST6-85WSIL	
	506L08	NST8-120WSIL	
	506L08-85	NST8-85WSIL	
	506L10-85	NST10-85WSIL	
507…	507-06-55	SFT6-55	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Guidewire Fr xx - Lg yy cm
	507-06-75	SFT6-75	
	507-06-85	SFT6-85	
	507-08	SFT8-120	
	507-08-55	SFT8-55	
	507-08-75	SFT8-75	
	507-08-85	SFT8-85	
	507-10	SFT10-120	
	507-10-85	SFT10-85	
	507-10-85B	SFT10-85B	
	507-12-85	SFT12-85	
507L…	507L08-85	SFT8-85W	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Guidewire Tungsten weighted Fr xx - Lg yy cm
	507L10-85	SFT10-85W	
508..	508-06	SJT6-120	ENTRAL* - ENFit® Nasojejunal Tube Polyurethane ORX Guidewire Fr xx - Lg yy cm

The following photos show one of the representative affected products. The image depicts the cap separated from the retaining strap following excessive patient manipulation.

WHITE CAP ATTACHED TO STRAP	WHITE CAP SEPARATED FROM STRAP

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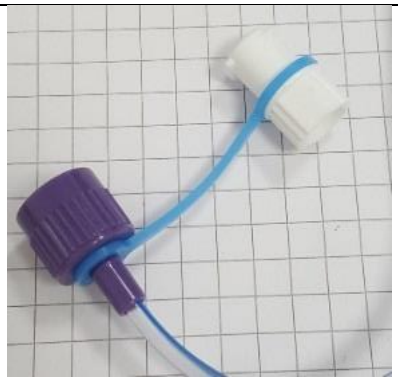

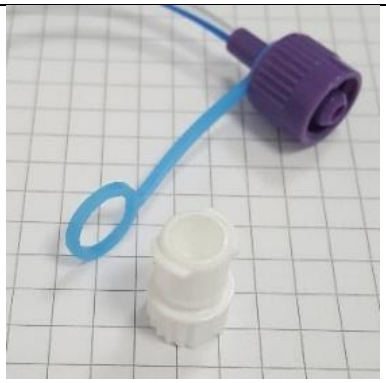

As a Clinical Facility/Customer, what should I do in response to this Field Safety Corrective Action Notice?

Immediate actions

1. Distribute this advisory notice to all departments within your clinical facilities who may have received the impacted NG Feeding Tubes.
2. Inform all concerned personnel about the potential choking risk associated with excessive patient manipulation of the retention strap and cap. At a minimum, this should include all clinicians and support staff who manage patients requiring Nasogastric Feeding.
3. Notify the caregivers/family members of patients who may use the impacted ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector.
4. Please review your clinical records to identify which patients, if any, were given any of the Maxter ENTRAL* NG Feeding Tubes referenced in this recall.

Scenario 1: Devices In-Use on Patients

- Assess the possibility to remove the recalled NG Feeding Tube. Consider the risks associated with removal and replacement of the NG Feeding tube relative to the risk associated with separation of the white cap and choking (i.e., less than 4 per million reported).
    - Please note that the risk of the cap separating from the retention strap is greatest during feeding of patients who have the potential strength and dexterity to cause separation of the cap.
- If the risk of replacing the recalled Maxter ENTRAL* NG Feeding Tube is acceptable, please use your established clinical procedures to remove the NG Tube and replace with an appropriate feeding tube.
- If the risk of replacing the recalled Maxter ENTRAL* NG Feeding Tube is not acceptable, then DO NOT remove the Maxter Enteral NG Feeding tube and take the following precautions:
    - Take action to ensure that the patient is not able to reach or manipulate the White Cap, catheter, or connector strap.
    - **Monitor the patient frequently during extended feeding durations.**
    - In case you experience any incident, please report the incident to Maxter Catheters at camille.chavy@hyh.com

Scenario 2: Devices Within Clinical Inventory

- Identify unused inventory of the Maxter ENTRAL* NG Feeding Tubes referenced in this recall within your stock and quarantine all unused units.

For both scenarios stated above

- Please complete the **Recall Customer Response Form** provided in **Annex 1** and return it within five (5) business days of receipt via e-mail to camille.chavy@hyh.com or fax to No: +33 4 91 46 73 48.

Maxter Catheters is implementing design enhancements to these products to address this issue and further reduce the risk of White Cap separation from the retention strap due to excess manipulation. If you require further assistance, please contact your Maxter Catheters Representative. The Competent Authorities in your country have been informed of this Field Safety Corrective Action. Please be informed that the Competent Authorities can request from you records associated with the affected products mentioned in this Field Safety Corrective Action.
We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your sales representative.

We thank you for your assistance.
Sincerely,
Maxter Catheters

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Annex 1: Recall Customer Response Form

Please complete this form and FAX to No: +33 4 91 46 73 48, or email to camille.chavy@hyh.com within 5 business days of receipt.

Using the following table please indicate which Product Reference Numbers of the impacted devices remain in your facility inventory along with quantities of each. If your facility does not have remaining inventory for any specific Reference Number category, enter zero (0) in the corresponding row.
Our records indicate we have shipped to you the following product references:

Maxter Product Reference Numbers	**Enter Each Reference Number and Quantity Quarantined** (e.g. *503-08-B10 = 12 units or enter "0" if none remaining, and please indicate if the quantity mentioned is in units, box or carton)*	
	Units	**Cases**
503-##-## 503T##-## 503TL##-##		
505-##-##		
506-##-## 506L##-##		
507-##-## 507L##-##		
508-##-##		

Please return this form to the above fax number as soon as possible. We expressly point out that the reply is mandatory, as the competent authority can request proof of the whereabouts of the goods in individual cases. Your Maxter / Halyard representative will contact you after reception of this form duly completed and can provide you additional details regarding return of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector and future availability of corrected product.

[ ] **I certify that this facility has read and understood the information provided in the Field Safety Corrective Action Notice, and the information provided in this notice will be distributed to the appropriate clinical staff and patient caregivers who are known to use the impacted ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector referenced.**

Facility Information	**Contact Person Completing Form**
(Facility Name)	(Name/Signature of Person Completing Form)
(Facility Address)	(Phone Number)